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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,003	09/09/2003	Frank N. Chang	06056-0314 US1	3509
23973 7590 09/14/2007 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			EXAMINER OLSEN, KAJ K	
			ART UNIT 1753	PAPER NUMBER
			MAIL DATE 09/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/659,003	Applicant(s) CHANG ET AL.	
	Examiner Kaj K. Olsen	Art Unit 1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 and 43-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-82, 93-98, 101, 102 and 105 is/are allowed.
- 6) ☒ Claim(s) 1-5, 8-10, 15-17, 22-30, 32, 34-41, 43-69, 83-92, 99, 100, 103, 104 is/are rejected.
- 7) ☒ Claim(s) 6, 7, 11-14, 18-21, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>6-25-2007</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-5, 8-10, 15-17, 22-30, 37-39, 41, 43-48, 63-66, 83-87, 103, and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong et al (Hwahak Konghak, 29(4), 1991, pp. 457-462) in view of Harrington et al (USP 5,637,202) and Nerenberg (USP 3,930,973). The examiner is citing the certified translation of Hong for this office action. However, because the examiner has already emailed the applicant a copy of this translation, the Office will not be providing a copy of it with this office action. Nerenberg is being cited and relied on for the first time with this office action. Its use here was necessitated by the applicant's amendment to the claims.

3. Hong discloses an electrophoresis system and method for the separation of proteins comprising a low conductivity organic solvent comprising at least one base solvent (propylene glycol, propylene carbonate), and at least one conductivity enhancer (N-methylacetamide, tetrahydrofuryl alcohol). Hong also discloses the use of a polymeric membrane (i.e. paper) that is compatible with the low conductivity organic solvent, and an electrophoresis apparatus which comprises at least one electrophoresis unit for containing the buffer and membrane and a power supply capable of generating an electric current in the at least one electrophoresis unit. See the

Art Unit: 1753

abstract, fig. 1 and sections 2.1 and 2.2. Hong does not explicitly disclose that the paper has a high-protein binding capacity. Applicant suggests on p. 4, ll. 4-10 that conventional electrophoresis papers do not possess high protein binding, Lederer actually evidences that the protein-binding qualities of electrophoresis paper can vary greatly with some papers having rather substantial protein binding. See p. 28. However, to the applicant's benefit, the examiner will presume the filter paper utilized by Hong would not meet the applicant's claimed high-protein binding. However, Harrington teaches that paper electrophoresis papers have been found lacking in the prior art and proposes the use of other polymeric membranes that have more uniform pore sizes and distributions providing for more accurate and reproducible electrophoretic separations. See col. 1, ll. 29-36 and col. 3, ll. 42-54. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Harrington for the system of Hong in order to provide an electrophoretic medium providing higher accuracy and reproducibility. With respect to the membranes Harrington providing high-protein binding, Harrington's preferred membrane is polyvinylidene difluoride (PVDF), which the instant invention evidences has high-protein binding capabilities (see claim 29).

4. With respect to the new limitations of claims 1 and 43, Hong further discloses a platform (see fig. 1), but did not explicitly recite where the membrane is no more coextensive than the length and width than said platform. Rather, Hong draped the ends of the membrane over the platform into the buffer solution so as to establish electrical connection to the buffer. However, it has been well established that electrical and solution connections for membrane electrophoresis can also be made via wicks. In particular, Nerenberg discloses the use of wicks (22, 23) that are

Art Unit: 1753

disposed below and in direct contact with the membrane 21 wherein both of the wicks are in direct contact with the buffer. Because, Nerenberg relies on wicks for the electrical connection, the membrane for the electrophoresis need not be more coextensive in length or width than the platform. See fig. 1 and col. 3, ll. 50-62. Because both Hong and Nerenberg teach methods for providing fluid and electrical contact between the electrodes and the membrane for electrophoresis, it would have been obvious to one of ordinary skill in the art at the time the invention was being made to substitute the wicking system of Nerenberg for the system relied on by Hong to achieve the predictable result of having the appropriate electrophoretic connections be established. Moreover, the use of wicks separate from the membrane itself allows one to tailor both the electrophoretic and wicking properties of the electrophoretic system separately. In particular, even though Nerenberg utilized cellulose acetate for both the membrane and the wicks, Nerenberg utilized different forms of cellulose acetate for both the membrane and the wick (col. 3, ll. 50-62), presumably because Nerenberg desired different performance for each of the membrane and wick. This is an advantage over the system of Hong where one cannot tailor the wicking and electrophoretic functions separately as both functions have to be provided by the same material.

5. With respect to the various dependent claims, see the previous office action for a discussion of these.

6. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Nerenberg as applied to claim 28 above, and further in view of Yoshida et al (USP 5,068,019). Yoshida is being cited and relied on for the first time with this office action. Its use here was necessitated by the amendment to claim 32.

Art Unit: 1753

7. The references set forth all the limitations of the claims, but did not explicitly set forth the use of a vinyl polymer of polyvinyl chloride. Yoshida teaches in an alternate use of a porous membrane of polyvinyl chloride as an electrophoretic support. See col. 4, ll. 52-63. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yoshida for the system of Hong, Harrington, and Nerenberg because the substitution of one known electrophoretic support for another requires only routine skill in the art.

8. Claims 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong, Harrington, and Nerenberg as applied to claim 24 above, and further in view of Hiratsuka et al (USP 4,128,470).

9. The references set forth all the limitations of the claims, but did not explicitly set forth any of the listed polymers. Hiratsuka discloses in an alternate electrophoresis system that nylon can also be utilized as an electrophoretic support. See example 3 at col. 8, l. 56 through col. 9, l.

4. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Hiratsuka for the system of Hong, Harrington, and Nerenberg because the substitution of one known electrophoretic support for another requires only routine skill in the art. With respect to the use of particular concentrations of amine termination, because Hiratsuka relies on a alcohol soluble form of nylon, the use of amine-terminated nylon would have been obvious so as to facilitate that solubility.

10. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Nerenberg as applied to claim 1 above, and further in view of Bambeck et al (USP 4,909,918).

Art Unit: 1753

11. The references set forth all the limitations of the claims, but did not explicitly recite the use of vertical electrophoresis. Bambeck teaches that vertical electrophoresis typically provides cleaner separations and smoother flow of the macromolecular mixture. See col. 1, ll. 37-44. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Bambeck for the system of Hong, Harrington, and Nerenberg so as to have cleaner separations and smoother fluid flow.

12. Claims 49-62 and 88-92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Nerenberg as applied to claims 43, 46 and 86 above, and further in view of Manian et al (USP 5,137,609).

13. The references set forth all the limitations of the claims, but did not explicitly recite the step of detecting protein-binding interactions. Manian teaches the use of fluorescently labeled antibodies for the purpose of detecting the presence of certain proteins-binding interactions in biological samples. See col. 8, ll. 13-44. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Manian for the method of Hong, Harrington, and Nerenberg so that particular proteins may be specifically labeled and detected thereby increasing the selectivity of the protein assay.

14. Claims 67-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Nerenberg as applied to claim 43 above, and further in view of Allen et al (International Journal of Pharmaceutics 187, 1999, pp. 259-272).

15. The references set forth all the limitations of the claims, but did not explicitly recite the use of samples taken at different time points. Allen discloses that electrophoresis can be utilized for the determining the integrity of the protein sample under storage. See section 3.2 and fig. 8

Art Unit: 1753

where a non-degraded sample is compared with samples from different time points (i.e. after 6 weeks of storage). It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Allen for the method of Hong, Harrington, and Nerenberg so as to extend the utility of the electrophoresis method to a determination of protein degradation.

16. Claim 99 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Yoshida.

17. With respect to this new claim, Hong and Harrington set forth all the limitations of the claims (see the rejection of claim 43 from the previous office action), but did not explicitly recite the use of a base solvent consisting of one of the set forth groupings. However, the set forth groupings include the use of either ethylene glycol or butylene glycol, which differ from the base solvent of Hong (i.e. propylene glycol) by only one CH₂ unit in either direction and Hong did not stress any criticality to the particular propylene form of glycol. Yoshida teaches that both ethylene glycol and butylene glycol (termed "tetramethylene glycol") are considered equivalent to propylene glycol as a wetting agent for an electrophoretic medium. See col. 6, ll. 16-24. It would have been obvious to one of ordinary skill in the art at the time the invention was being made to utilize the teaching of Yoshida for the method of Hong and Harrington because the substitution of one known form of glycol for another would have required only routine skill in the art.

18. Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hong in view of Harrington and Selai et al (USP 6,866,772). Selai is being cited and relied on for the first time with this office action. Its use here was necessitated by this new claim.

Art Unit: 1753

19. Hong and Harrington set forth all the limitations of the claim and Hong teaches the use of a combination of N-methylacetamide and tetrahydrofurfuryl alcohol. See section 2.1. N-methylacetamide differs from acetamide, N-methylformamide, or N-methylpropionamide in only the presence of a CH₂ unit, and Hong disclose no criticality to its particularly chosen form of amide hydrocarbon. Selai teaches that acetamide, N-methylformamide or N-methylpropionamide are considered analogous solvents to N-methylacetamide (col. 2, ll. 62-67), and one possessing ordinary skill in the art would have been motivated to rely on the teaching of Selai for the method of Hong and Harrington because the substitution of one known component for an analogous art recognized component would have required only routine skill in the art.

Allowable Subject Matter

20. Claims 70-82, 93-98, 101, 102, and 105 are allowed.

21. Claims 6, 7, 11-14, 18-21, 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Information Disclosure Statement

22. The IDS resubmitted on 6-25-2007 has been considered. The examiner lined through the citation to Harrington because the examiner has already cited this teaching in the previous PTO-892.

Response to Arguments

23. Applicant's arguments submitted on 6-25-2007 have been fully considered but are moot in view of the new ground(s) of rejection relying on the teaching of Nerenberg.

Conclusion

24. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kaj Olsen whose telephone number is (571) 272-1344. The examiner can normally be reached on Monday through Friday from 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen, can be reached on 571-272-1342. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Art Unit: 1753

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AU 1753
September 11, 2007



KAJ K. OLSEN
PRIMARY EXAMINER